JS: 2/26/21

[redacted]

[redacted]

[redacted]

June 7, 1989

EXPRESS MAIL-RETURN RECEIPT REQUESTED - B006 866 98N

89 JUL -3 AM 9:01
OTS-USC-MAIL CONTROL OFFICE

Document Control Officer
Office of Toxic Substances, TS-793
Document Processing Center
U. S. Environmental Protection Agency
401 M Street, S. W.
Washington, DC 20460

51890000867
P89-867

Dear Sir:

Enclosed is a Premanufacture Notice for your review. It is provided in two (2) forms:

1. The original with confidential portions so marked, and

2. A sanitized version for the public files.

The Premanufacture Notice is numbered [redacted] The PMN fee of $2,500 has been sent to the H. Q. Accounting Operations Board with the [redacted] identifying number on it.

If you need any more information, please contact me.

[redacted]

[redacted]

[redacted]

[TS-FX0124]

CONFIDENTIAL

O.M.B. No. 2070-0012: Approval Expires 3-3-86

United States Environmental Protection Agency

PREMANUFACTURE NOTICE
FOR NEW CHEMICAL SUBSTANCES

When completed send this form to

DOCUMENT CONTROL OFFICER
OFFICE OF TOXIC SUBSTANCES, TS-793
U.S. E.P.A.
401 M STREET, SW
WASHINGTON, D.C. 20460

AGENCY USE ONLY

Date of receipt 03 JUL -3 AM 9:02 GMS-DOCUMENT CONTROL OFFICE

Enter the total number of pages in the Premanufacture Notice 156

Document control number 51890000867

EPA case number P89-867

EPA-OTS 000667703T

GENERAL INSTRUCTIONS

You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.

Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (**Instructions Manual**).

Part I — GENERAL INFORMATION

You must provide the chemical identity of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit the identity for you, but your submission will not be complete and review will not begin until EPA receives this information.

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

You may need additional copies of part II, sections A and B if there are several manufacture, processing, or use operations that you will describe in the notice. You should reproduce these sections as needed.

Part III — LIST OF ATTACHMENTS

You should attach additional sheets if you do not have enough space on the form to answer a question fully. In part III, list these attachments, any test data or other data, and any optional information that you include in the notice.

OPTIONAL INFORMATION

You may include in the notice any information that you want EPA to consider in evaluating the new substance. The **Instructions Manual** identifies categories of optional information that you may want EPA to review.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notice as confidential, you must provide a sanitized version of the notice, including attachments, to EPA with your submission. For additional instructions on claiming information as confidential, read the **Instructions Manual.**

Indicate below the categories of information you have claimed as confidential in the notice and the type of notice.

1	[X] SUBMITTER IDENTITY	[X]	PMN
2	[X] CHEMICAL IDENTITY	[ ]	TMEA
3	[X] PRODUCTION VOLUME	[ ]	SNUR
4	[X] USE INFORMATION	[ ]	Exemption — *Specify*
5	[X] PROCESS INFORMATION		
6	[X] PORTIONS OF A MIXTURE		
7	[X] OTHER INFORMATION		

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data, not summaries of data, must be submitted if they do not appear in the open literature. Following are examples of test data and other data. You should submit these data according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test data

- **Environmental fate data**
  - Spectra (UV, visible, and infrared)
  - Density of liquids and solids
  - Water solubility
  - Melting point/melting range
  - Boiling point/boiling range
  - Vapor pressure
  - Partition coefficient, n-octanol/water
  - Biodegradation
  - Hydrolysis (as a function of pH)
  - Photochemical degradation
  - Adsorption/desorption to soil types
  - Dissociation constant
  - Other physical/chemical properties
- **Health effects data**
  - Mutagenicity
  - Carcinogenicity
  - Teratogenicity
  - Acute toxicity
  - Repeated dose toxicity
  - Metabolism studies
  - Sensitization
  - Irritation
- **Environmental effects data**
  - Microbial and algal toxicity
  - Terrestrial vascular plant toxicity (e.g., seed germination studies, growth inhibition)
  - Acute and chronic toxicity to animals (e.g., fish, birds, mammals, invertebrates)

Other data

- **Risk assessments**
- **Structure/activity relationships**
- **Test data not in the possession or control of the submitter**

CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in part I, section A, subsection 1a of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities solely for research and development, the substance identified in part I, section B.

2. All information provided in this notice is complete and truthful as of the date of submission.

3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

4. The company named in Part 1, section A has remitted the fee specified in 40 CFR 700.45(b).

		Confi-dential
Sig[redacted]	Date [redacted]	[redacted]
Signature of agent — *(if applicable)*	Date	[redacted]

Part I — GENERAL INFORMATION

Section A — SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

			Confi-dential
1a. Person submitting notice	Name of authorized official [redacted]	[redacted] gy & Regulatory Affairs	X
	Company [redacted]		
	Mailing address (number and street) [redacted]		
	City, State, ZIP code [redacted]		
[redacted] *applicable)*	[redacted]	Title	
	Company		
	Mailing address (number and street)		
	City, State, ZIP code		

c. *If you are submitting this notice as part of a joint submission, mark (X) this box.* → ☐

[redacted]

3. If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number →		*Mark (X) if none* →	X
4. If you have submitted a test-marketing exemption (TME) application for the chemical substance covered by this notice, enter the TME number assigned by EPA →		*Mark (X) if none* →	X
5. If you have submitted a bona fide request for the chemical substance covered by this notice, enter the bona fide request number assigned by EPA →		*Mark (X) if none* →	X

6. Type of Notice — *Mark (X)* ☒ Manufacture ☐ Import

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete either item 1 or 2 as appropriate. Complete all other items.

If another person will submit chemical identity information for you, mark (X) the box at the right. → ☐
Identify the name, company, and address of that person in a continuation sheet.

Confi-dential

[redacted]

☐ *Mark (X) this box if you attach a continuation sheet.*

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY INFORMATION — Continued

2. Polymers (For a definition of polymer, see the **Instructions Manual**.)

Confi-dential

a. Indicate the **lowest** number-average molecular weight composition of the polymer you intend to manufacture. Indicate the **maximum** weight percent of low molecular weight species below 500 and below 1,000 absolute molecular weight of that composition. Describe the methods of measurement or the bases for your estimates.

N/A

☐ *Mark (X) this box if you attach a continuation sheet.*

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) — Provide the chemical name and CAS Registry Number of each monomer or other reactant used in the manufacture of the polymer.
(2) — Mark (X) this column if entry in column (1) is confidential.
(3) — Indicate the **typical** weight percent of each monomer or other reactant in the polymer.
(4) — Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(5) — Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) — Indicate the **maximum** weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.
(7) — Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant and CAS Registry Number (1)	**Confi-dential** (2)	Typical composition (3)	Identity *Mark (X)* (4)	**Confi-dential** (5)	Maximum residual (6)	**Confi-dential** (7)
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	

☐ *Mark (X) this box if you attach a continuation sheet.*

c. Provide a representative structural diagram of the polymer, if possible.

☐ *Mark (X) this box if you attach a continuation sheet.*

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY INFORMATION — Continued

3. Impurities

(a) — Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposes. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."

(b) — Estimate the **maximum** weight percent of each impurity. If there are unidentified impurities, estimate their total weight percent.

[redacted]

%

☐ *Mark (X) this box if you attach a continuation sheet.*

[redacted]

6. Generic chemical name — If you claim chemical identity as confidential, enter the generic chemical name that you developed with EPA during prenotice communication. If you have not developed a generic name with EPA, provide a generic name that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Read the TSCA Chemical Substance Inventory, Initial Inventory, Volume I for guidance on developing generic names.

Halogenated Alkyl Aromatic

☐ *Mark (X) this box if you attach a continuation sheet.*

[redacted]

☐ *Mark (X) this box if you attach a continuation sheet.*

Part I — GENERAL INFORMATION — Continued

Section C — PRODUCTION, IMPORT, AND USE INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume — Estimate the **maximum** production volume during the first 12 months of production. Also estimate the **maximum** production volume for any consecutive 12-month period during the first three years of production.

Maximum first 12-month production (kg/yr)	Maximum 12-month production (kg/yr)	Confidential
[redacted]	[redacted]	

2. Use Information — You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" box next to any item you claim as confidential.

a. (1) — Describe each intended category of use of the new chemical substance by function and application.
(2) — Mark (X) this column if entry in column (1) is confidential.
(3) — Estimate the percent of total production for the first three years devoted to each category of use.
(4) — Mark (X) this column if entry in column (3) is confidential.
(5) — Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(6) — Mark (X) this column if entry in column (5) is confidential.
(7) — Mark (X) whether the use is site-limited, industrial, commercial, or consumer. Mark more than one column if appropriate.
(8) — Mark (X) this column if entry(ies) in column (7) is (are) confidential.

Read the **Instructions Manual** for examples.

Category of use (1)	Confidential (2)	Production (percent) (3)	Confidential (4)	Formulation (percent) (5)	Confidential (6)	Mark (X) appropriate column(s) (7)				Confidential (8)
						Site-limited	Industrial	Commercial	Consumer	
[redacted]										

☐ *Mark (X) this box if you attach a continuation sheet.*

b. Generic use description — If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the **Instructions Manual** for examples of generic use descriptions.

Plastic Additive

☐ *Mark (X) this box if you attach a continuation sheet.*

3. Hazard Information — Include in the notice a copy or reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person regarding protective equipment or practices for the safe handling, transport, use, or disposal of the new chemical substance. List in part III any hazard information you include.

☒ *Mark (X) this box if you attach hazard information.*

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A — INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control.

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Operation description

a. Identity— Enter the identity of the site at which the operation will occur. | **Confidential**

[redacted]

If the same operation will occur at more than one site, enter the number of sites. → [redacted]
Identify the additional sites on a continuation sheet.

☐ *Mark (X) this box if you attach a continuation sheet.*

b. Type — *Mark (X)*

1 ☒ Manufacturing 2 ☐ Processing 3 ☐ Use

c. Amount and Duration — *Complete 1 or 2 as appropriate*

[redacted]

d. Process description

(1) Diagram the major unit operation steps and chemical conversions.

(2) Provide the identity, the approximate weight (by kg/day or kg/batch), and entry point of all feedstocks (including reactants, solvents, and catalysts).

(3) Identify by number the points of release to the environment of the new chemical substance.

[redacted]

☐ *Mark (X) this box if you attach a continuation sheet.*

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE — Continued

Section A — INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER — Continued

2. Occupational Exposure — You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.
(1) — Describe the activities in which workers may be exposed to the new chemical substance. Include activities in which workers wear protective equipment.
(2) — Mark (X) this column if entry in column (1) is confidential.
(3) — Indicate the physical form(s) of the new chemical substance at the time of exposure.
(4) — Mark (X) this column if entry in column (3) is confidential.
(5) — Estimate the maximum number of workers involved in each activity.
(6) — Mark (X) this column if entry in column (5) is confidential.
(7) and (8) — Estimate the maximum duration of the activity for any worker in hours per day and days per year.
(9) — Mark (X) this column if entries in columns (7) and (8) are confidential.

Worker activity (1)	Confidential (2)	Physical form(s) (3)	Confidential (4)	Maximum number (5)	Confidential (6)	Maximum duration Hrs/day (7)	Maximum duration Days/yr (8)	Confidential (9)
[redacted]								

☐ *Mark (X) this box if you attach a continuation sheet.*

3. Environmental Release and Disposal — You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.
(1) — Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) — Estimate the amount of the new chemical substance released directly to the environment or into control technology (in kg/day or kg/batch).
(3) — Mark (X) this column if entries in columns (1) and (2) are confidential.
(4) — Identify the media (air, land, or water) to which the new substance will be released from that release point.
(5) — Describe control technology, if any, that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method.
(6) — Mark (X) this column if entries in columns (4) and (5) are confidential.
(7) — Identify the destination(s) of releases to water.

Release Number (1)	Amount of new substance released (2)	Confidential (3)	Media of release (4)	Control technology (5)	Confidential (6)
[redacted]					

(7) Mark (X) the destination(s) of releases to water. ☐ POTW (publicly owned treatment works) ☐ Navigable waterway ☐ Other — *Specify*

☐ *Mark (X) this box if you attach a continuation sheet.*

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE — Continued

Section B — INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete section B for each type of processing or use operation involving the new chemical substance at sites you do not control.

*To claim information in this section as confidential, circle or bracket the **specific** information that you claim as confidential.*

Operation description

Describe the typical processing or use operation. Identify the unit operation steps which may occur during the operation. Estimate the number of sites at which the operation is likely to occur. Identify situations in which worker exposure to and/or environmental release of the new chemical substance may occur. Estimate the percent of new chemical substance as formulated in products manufactured for commercial purposes in the operation or as used in the operation. Estimate the number of workers exposed and the duration of exposure. Identify controls which limit worker exposure and environmental release if typically used. Identify byproducts which may result from the operation.

[redacted] is used by our customers as an ingredient in formulated products. A number of [redacted] The specifics of operational control are known only to the formulators or compounders involved.

☐ *Mark (X) this box if you attach a continuation sheet.*

Part III — LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment.

Mark (X) the "Confidential" box next to any attachment **name** you claim as confidential. Read the **Instructions Manual** for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

Attachment name	Attachment page number(s)	Confidential
[redacted]		

☐ *Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.*

APPENDIX B

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the page of the notice on which the property appears, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. You are not required to submit this worksheet; however, EPA recommends that you do so, as it will simplify review and ensure that confidential information is properly protected. You should submit this worksheet as a supplement to your submission of test data. This worksheet is **not** a substitute for submission of test data.

Property (a)	*Mark (X) if provided*	Page number (b)	Value (c)	Confidential *Mark (X)* (d)
1. Vapor pressure @ Temperature _____ °C			torr	
2. Density/relative density			g/c^3	
[redacted]				
4. Melting temperature			[redacted]	
5. Boiling/sublimation temperature			°C	
6. Spectra [redacted]				
7. Dissociation constant				
8. Particle size distribution				
9. Octanol/water partition coefficient				
10. Henry's Law constant				
11. Volatilization from water				
12. Volatilization from soil				
13. pH				
14. Flammability				
15. Explodability				
16. Adsorption/desorption				
17. Other — *Specify*				
18.				
19.				
20.				
21.				
22.				

TOXICITY SUMMARY

[redacted] has been tested in a series of acute toxicity studies and in the Ames Salmonella mutagenicity assay. The compound was practically nontoxic to rats and rabbits on oral or dermal exposure, respectively (Rat Oral LD50 > 5000 mg/kg, Rabbit Dermal LD50 > 2000 mg/kg). [redacted] was non-irritating to the skin or eyes of rabbits. It was negative in the Ames Salmonella assay using the five standard strains both with and without activation.

CONFIDENTIAL AS MARKED [ ]

[redacted]

[redacted]

June 7, 1989

HEALTH RISK EVALUATION

[redacted] has evaluated the health risks presented by the manufacturing of [redacted]. We conclude this new chemical substance will not present unreasonable risk of injury to health. Acute toxicology studies indicate the compound has a very low order of toxicity. In addition, essentially no exposure will occur because the material will be manufactured and handled in a closed system. The only potential exposures are during activities related to quality control sampling, product packaging, and process equipment cleaning. During these times, industrial hygiene practices will protect against worker overexposure. Employees engaged in collection of quality control samples will wear hand and eye protection. Workers engaged in packaging and cleaning will use disposable coveralls, dust respirators, gloves and eye protection. We believe these measures will provide adequate protection against overexposure.

[redacted]